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July 8, 1999

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

Dear Sir/Ms:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999.

As I understand it, in its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice. It also appears to infringe on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU should therefore be amended.

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. IT IS DIFFICULT TO SEE HOW THIS IS WOULD BE A SAFETY ISSUE. As a governmental agency, the FDA also has a responsibility to be accountable to the people. I believe in light of the above that the MOU needs amendment.

Thank you for your attention.

Sincerely,

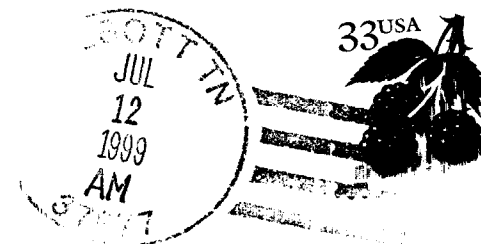


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